

MINERAL SUNSCREEN SPF 50- zinc oxide, titanium dioxide stick
TOPCO ASSOCIATES LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TOPCARE EVERYDAY MINERAL SUNSCREEN STICK SPF 50

Active ingredients

Titanium Dioxide 7.0%, Zinc Oxide 4.7%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use

- on damaged or broken skin.

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash occurs.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months of age: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Other information

- protect this product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

beeswax, butyloctyl salicylate, caprylyl glycol, cetyl alcohol, euphorbia cerifera (candelilla) wax, isopropyl palmitate, isostearic acid, neopentyl glycol diethylhexanoate, ozokerite, paraffin, silica

Label

Topcare Everyday Mineral Sunscreen Stick SPF 50

NDC 36800-956-28

1.5 oz (42 g)



mineral sunscreen stick

zinc oxide • titanium dioxide

BROAD SPECTRUM SPF 50 SUNSCREEN UVA/UVB

50

REEF CONSCIOUS†
OXYBENZONE, OCTINOXATE
& PARABEN FREE*

WATER RESISTANT (80 MINUTES)

NET WT 1.5 OZ (42 g)

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
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✓ QUALITY GUARANTEED

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 7.0% Zinc Oxide 4.7%	Sunscreen

†Formula is compliant with H1 SB2571.

*No parabens separately added to preserve this product.



Drug Facts (continued)

Uses • helps prevent sunburn • if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

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Rinse with water to remove.

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HINGE AREA

Drug Facts (continued)

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 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

Beeswax, Butyloctyl Salicylate, Caprylyl Glycol, Cetyl Alcohol, Euphorbia Cerifera (Candelilla) Wax, Isopropyl Palmitate, Isostearic Acid, Neopentyl Glycol Diethylhexanoate, Ozokerite, Paraffin, Silica.

Questions or comments?

Call toll free 1-888-423-0139

HINGE AREA

MINERAL SUNSCREEN SPF 50

zinc oxide, titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-956
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	70 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	47 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CANDELILLA WAX (UNII: WL0328HX19)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
CERESIN (UNII: Q1LS2UJO3A)	
WHITE WAX (UNII: 7G1J5DA97F)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
PARAFFIN (UNII: I9O0E3H2ZE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-956-28	42 g in 1 CONTAINER; Type 0: Not a Combination Product	10/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/19/2020	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 4/2021

TOPCO ASSOCIATES LLC